CERAMENT®

KEY CLINICAL EVIDENCE

The CERAMENT® platform of products promote and protect bone healing.

This is supported by over 240 publications and abstracts. Here is an overview of the key clinical and safety data on the following key indications:

- Chronic osteomyelitis
- Fracture-related infections
- Diabetic foot osteomyelitis
- Trauma
- Open Fracture
- Periprosthetic joint infections (PJI)
- Benign bone tumors and tumor-like lesions

Chronic Osteomyelitis

1. The Oxford Protocol Series

McNally et al. 'Mid- to long-term results of single-stage surgery for patients with chronic osteomyelitis using a bioabsorbable gentamicin-loaded ceramic carrier.' Bone Joint J. 2022;104-B(9):1095-1100.

Design: Prospective case series

Patient: 100 patients, mean age 51.6 years [range: 23–88]

Treatment: Single-stage protocol including debridement and application of CERAMENT G

Center: Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals, UK

Follow-up: 6.05 years [range: 4.4–8.4]

RESULTS

94% remained infection-free
6 patients with recurrent infection were revised and remained infection-free

3% fracture rate
(all within the first 11 months)

8/10 non-unions infection-free

5/5 arthrodeses healed

Ferguson et al. 'Radiographic and Histological Analysis of a Synthetic Bone Graft Substitute Eluting Gentamicin in the Treatment of Chronic Osteomyelitis.' J Bone Joint Infect. 2019;4:76-84.

Design: Prospective case series

Patient: 163 patients, mean age 51.6 years [range: 17.8–86.1]

Treatment: Single-stage protocol including debridement and application of CERAMENT G

Center: Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals, UK

Follow-up: 1.7 years [range: 1.0–4.7]

RESULTS

73.8% mean void-filling
at final follow-up

Histology revealed active biomaterial remodeling with osteoblast recruitment, formation of osteoid, woven and finally lamellar bone

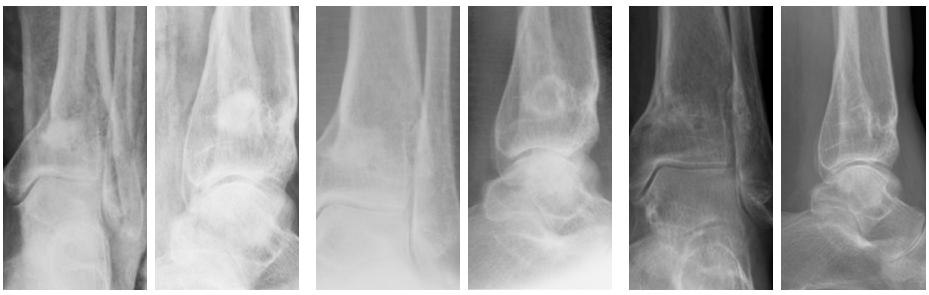


Figure 1. X-ray images from a patient with osteomyelitis in the distal tibia, which was debrided and filled with CERAMENT G. The two images on the far left show the defect filled with CERAMENT immediately post-operatively. Six weeks after surgery an active zone of remodeling is seen around the periphery of CERAMENT, known as the 'halo' sign (two center images) and 12 months after surgery (two images on the far right) CERAMENT is almost completely remodeled into new bone.

Chronic Osteomyelitis Cont.

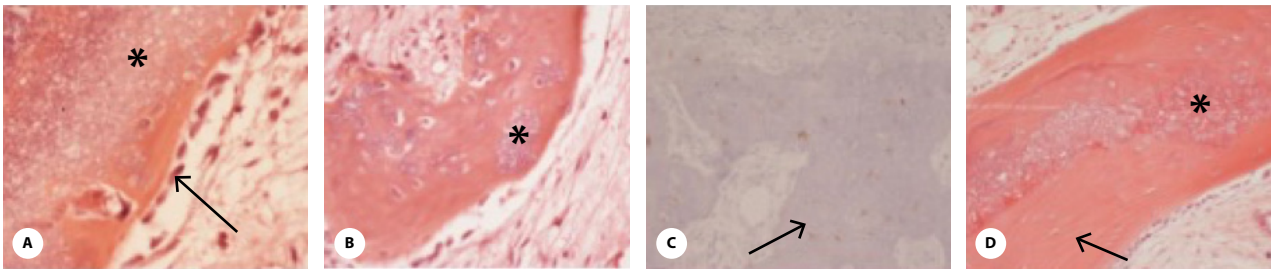


Figure 2. In early biopsies from between 9 days and 2 months after implantation of CERAMENT G, osteoblastic cells can be seen lining CERAMENT (image (a), black arrow) and surrounding it with an osteoid matrix (b, asterisk indicates CERAMENT), typical of early bone formation. Immunohistochemistry staining (c) confirms osteocytes are present in the matrix and expressing normal markers (black arrow). Two years after implantation (d) CERAMENT is completely incorporated into mature, lamellar bone.

Images from Ferguson et al. 'Radiographic and Histological Analysis of a Synthetic Bone Graft Substitute Eluting Gentamicin in the Treatment of Chronic Osteomyelitis.' J Bone Joint Infect. 2019;4:76-84 under Creative Commons Attribution 4.0 International License. No changes have been made.

2. Anugraha et al. 'End-capping of amputation stumps with a local antibiotic containing hydroxyapatite bio-composite - A report of 13 cases with chronic lower limb osteomyelitis.' J Orthop. 2020;17:124-126.

Design: Retrospective case series

Patient: 13 patients, mean age 59 years [range: 27–84]

Treatment: Amputation with CERAMENT G used as a medullary plug/end cap

Center: Wytheshawe Hospital, Manchester University NHS Foundation Trust, United Kingdom

Follow-up: Min. 12 months

RESULTS

All wounds healed without surgical site infection
21 days mean time to stump healing [range: 18–28]
No stump hematomas/seromas

3. Lorentzen et al. 'One-stage treatment of chronic osteomyelitis with an antibiotic-loaded biocomposite and a local or free flap'. Eur J Plast Surg. 2021;44:367-374.

Design: Retrospective case series

Patient: 11 patients, mean age 62 years [range: 39–79]

Treatment: Single-stage protocol including debridement, application of CERAMENT G and a local or free flap

Center: Department of Plastic Surgery, Herlev and Gentofte Hospital, University of Copenhagen, Denmark

Follow-up: 28 months [range: 15–42]

RESULTS

81.8% of patients (9/11) **healed uneventfully**

Two patients (18.2%) experienced partial or complete flap necrosis and required additional surgery (not due to CERAMENT)
No amputations

Fracture-Related Infection

1. Drampalos et al. 'Augmented debridement for implant related chronic osteomyelitis with an absorbable, gentamycin loaded calcium sulfate/hydroxyapatite biocomposite.' J Orthop. 2020;17:173-179.

Design: Prospective case series

Patient: 52 patients, mean age 53 years [range: 22–81]

Treatment: Single-stage protocol including debridement and application of CERAMENT G

Center: Department of Orthopaedics, Orthoplastic Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, UK

Follow-up: 17 months [range: 12–48]

RESULTS

92.3% remained infection-free The four (7.7%) recurrences included one below knee amputation

Fracture-Related Infection Cont.

2. Pesch et al. 'Treatment of fracture-related infection of the lower extremity with antibiotic-eluting ceramic bone substitutes: case series of 35 patients and literature review.' Infection. 2020;48:333–344.

Design: Prospective case series

Patient: 35 patients, mean age 56.4 years [range 37.8–75]

Treatment: Single- and two-stage protocol including debridement and application of CERAMENT G

Center: Department of Trauma Surgery, Klinikum Rechts der Isar, Technical University of Munich, Germany

Follow-up: 14.9 months [range: 2–40]

RESULTS

91.4% remained infection-free

Three recurrences and delayed wound secretion in 6 (17.1%) cases

No fractures

Mean 8.5 mRUS score of bone consolidation = 'in process'

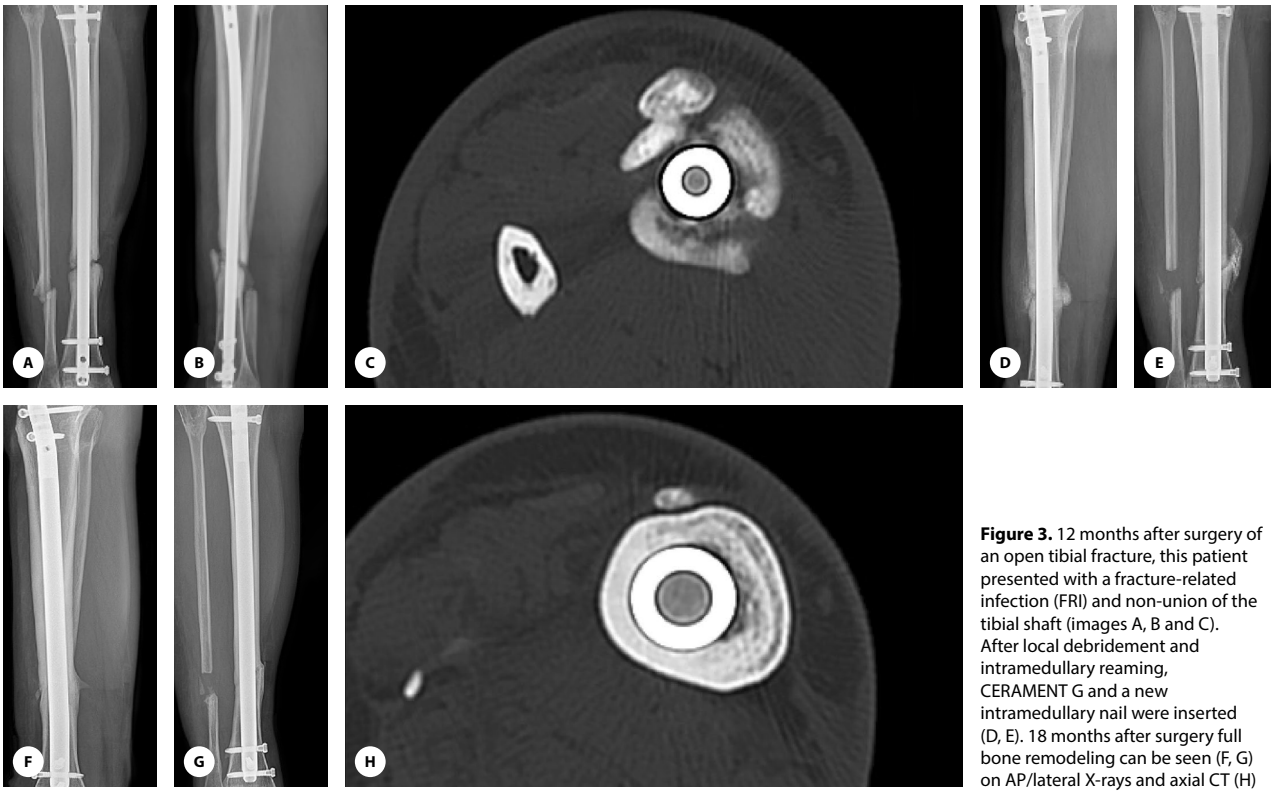


Figure 3. 12 months after surgery of an open tibial fracture, this patient presented with a fracture-related infection (FRI) and non-union of the tibial shaft (images A, B and C). After local debridement and intramedullary reaming, CERAMENT G and a new intramedullary nail were inserted (D, E). 18 months after surgery full bone remodeling can be seen (F, G) on AP/lateral X-rays and axial CT (H)

Diabetic Foot Osteomyelitis

1. Kavarthapu et al., 'Evaluation of Adjuvant Antibiotic Loaded Injectable Bio-Composite Material in Diabetic Foot Osteomyelitis and Charcot Foot Reconstruction', Journal of Clinical Medicine, 2023; 12.9, 3239.

Design: Retrospective, consecutive case series

Patient: 53 patients (54 feet), mean age 56 years [range: 27–83], two groups: (1) diabetic foot ulcer infection reaching the bone (n = 17), and (2) Charcot foot (n = 36)

Treatment: Implant augmentation, debridement and dead space management with CERAMENT G and CERAMENT V

Center: Department of Orthopedic Surgery, King's College NHS Foundation Trust, London, UK

Follow-up: 30 months [range: 12–98]

RESULTS

Diabetic foot ulcer infection

87% remained infection-free

Charcot foot

100% limb salvage rate

100% ulcer resolution

90% independent ambulation

Diabetic Foot Osteomyelitis Cont.

2. Niazi et al. 'Adjuvant antibiotic loaded bio composite in the management of diabetic foot osteomyelitis - A multicentre study'. Foot (Edinb). 2019;39:22-27.

Design: Retrospective case series

Patient: 70 patients, mean age 68 years [range: 22–88]

Treatment: Debridement and dead space management with CERAMENT G

Center: Department of Orthopedic Surgery, King's College NHS Foundation Trust, London, UK; Trauma and Orthopaedics department, Frimley Health NHS Foundation Trust, Surrey, UK

Follow-up: 10 months [range: 4–28]

RESULTS

90% remained infection-free

Seven patients required further treatment, five below knee amputation (cases with significant vascular compromise)

3. Drampalos et al. 'Single stage treatment of diabetic calcaneal osteomyelitis with an absorbable gentamicin loaded calcium sulphate/hydroxyapatite biocomposite: The Silo technique.' Foot (Edinb). 2018;34:40-44.

Design: Retrospective case series

Patient: 12 patients, mean age 68 years [range: 50–85]

Treatment: Silo technique with CERAMENT G

Center: Department of Orthopaedics, Orthoplastic Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, UK

Follow-up: 16 weeks [range: 12–18]

RESULTS

100% remained infection-free

One patient required subsequent flap operation. One case of prolonged wound leakage

No fractures

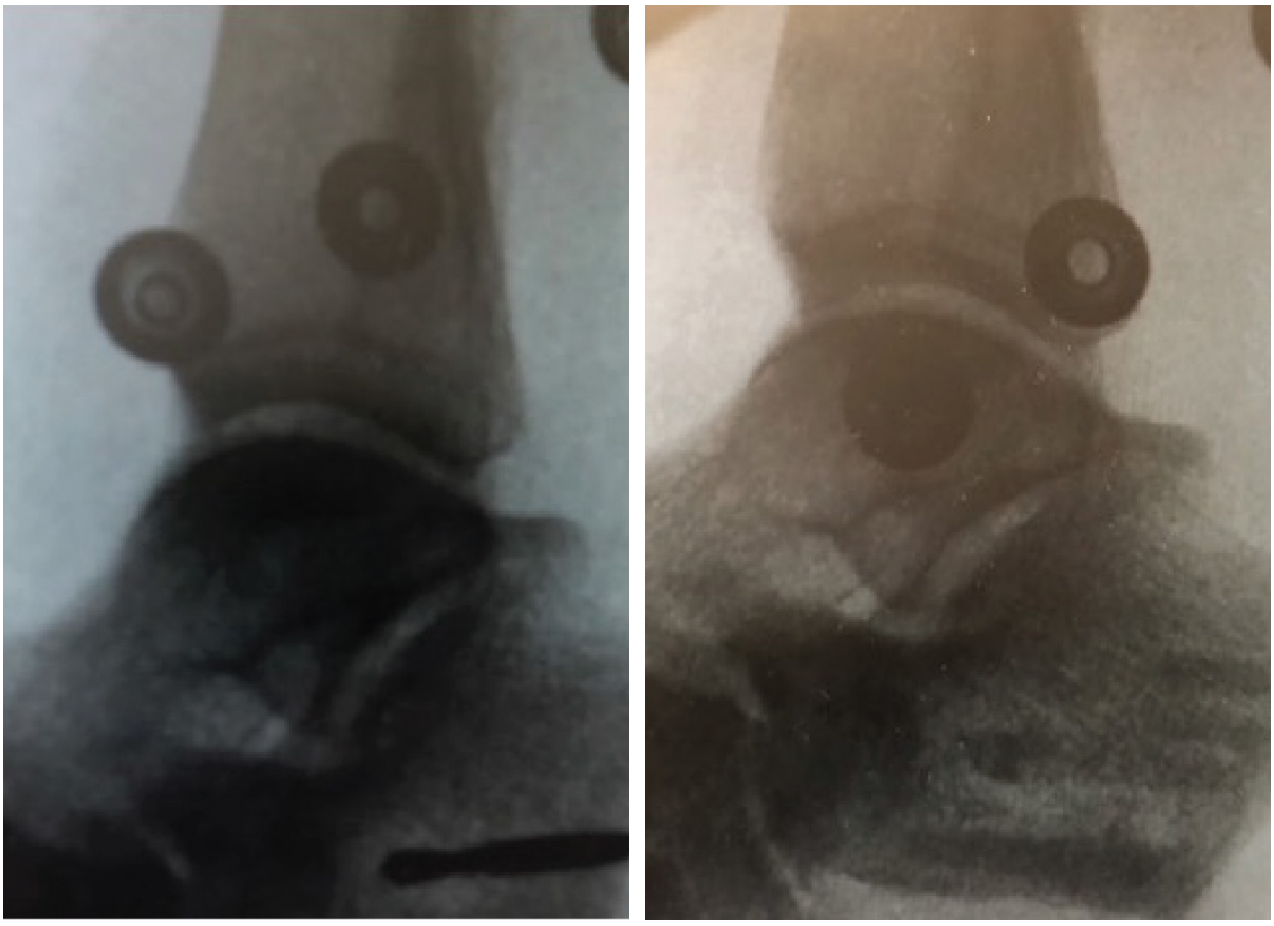


Figure 4. Images of an infected calcaneus, treated by surgery using the Silo technique and CERAMENT G. In this technique Silo type tunnels (four to five) are drilled into the calcaneus (left image) and the tunnels are then filled with CERAMENT G (right image)

Images of Silo Technique from Vasukutty et al.'Limb salvage surgery in diabetic foot infection:encouraging early results with a local antibiotic carrier.' The Diabetic Foot Journal. 2022;25(2):1-5

Diabetic Foot Osteomyelitis Cont.

4. Vasukutty et al. 'Limb salvage surgery in diabetic foot infection: encouraging early results with a local antibiotic carrier.' The Diabetic Foot Journal. 2022;25(2):1–5.

Design: Retrospective case series

Patient: 47 patients (48 feet), mean age 55 years [range: 34–83]

Treatment: Debridement and dead space management with CERAMENT G, with or without reconstructive surgery

Center: United Lincolnshire Hospitals NHS Trust, Boston, UK & East and North Hertfordshire Hospitals NHS Trust, Lincoln, UK

Follow-up: 33 months [range: 13–49]

RESULTS

94% limb salvage rate

88% infection control and healing (42/48 feet)

83% (39/47) mobilizing and fully weight bearing with custom-made shoes

Figure 5. Intraoperative images of application of CERAMENT. First the metatarsal is reamed (left picture), and then CERAMENT is injected by retrograde filling (right picture).

Images from Vasukutty et al. 'Limb salvage surgery in diabetic foot infection: encouraging early results with a local antibiotic carrier.' The Diabetic Foot Journal. 2022;25(2):1–5

Trauma

1. Hofmann et al. 'Autologous Iliac Bone Graft Compared with Biphasic Hydroxyapatite and Calcium Sulfate Cement for the Treatment of Bone Defects in Tibial Plateau Fractures: A Prospective, Randomized, Open-Label, Multicenter Study'. J Bone Joint Surg Am. 2020;102(3):179-193.

Design: Prospective randomized controlled multi-center trial (RCT)

Indication: Acute traumatic depression fractures of the proximal tibia (limited to AO type 41-B2 & B3)

Patient: 135 patients, mean age 46.7 years [range: 18–65]

Treatment: Autologous iliac bone graft (AIBG) or CERAMENT BONE VOID FILLER

Center: 20 orthopedic trauma centers in Germany

RESULTS

CERAMENT BONE VOID FILLER is as good as autograft in terms of bone remodeling and patient-reported outcome measures (PROMS)

CERAMENT BONE VOID FILLER patients had significantly less post-op pain and blood loss, and a trend towards shorter duration of surgery

CERTiFy
CERAMENT™ Tibia Fracture Study

Open Fracture

1. Henry et al., 'Long-Term Follow-Up of Open Gustilo-Anderson IIIB Fractures Treated With an Adjuvant Local Antibiotic Hydroxyapatite Bio-Composite', Cureus, 2023; 15.5

Design: Retrospective review

Indication: Open Gustilo-Anderson IIIB fractures

Patient: 81 patients, mean age 39.5 years [range: 9–88]

Treatment: Single-stage 'Fix and Flap' with CERAMENT G

Center: Department of Orthopaedics, Orthoplastic Unit, Wythenshawe Hospital, Manchester University NHS Foundation Trust, UK

Follow-up: 55.8 months [range: 11–101 months]

RESULTS

96.3% limb salvage rate

3.7% deep infection rate

96% achieved union

82% primary union

5.6% non-union that required revision surgery and went on to heal

Periprosthetic Joint Infections (PJI)

1 KEY STUDY

1. Logoluso et al. 'Calcium-based, antibiotic-loaded bone substitute as an implant coating: a pilot clinical study.' J Bone Joint Infect. 2016;1:59-64.

Design: Prospective series

Patient: 20 patients, mean age 67.8 years [range: 40–89]

Treatment: Two-stage hip and knee revision surgery with application of CERAMENT G or CERAMENT V

Center: Dept of Reconstructive Surgery of Osteo-Articular Infections C.R.I.O Unit, I.R.C.C.S. Galeazzi Orthopaedic Institute, Milan, Italy

Follow-up: 18.1 months [range: 12–36]

RESULTS

95% remained infection-free

One patient (5%) had recurrence of infection (infected tibial head fracture with Pseudomonas aeruginosa).

No radiographic signs of loosening or subsidence in any patient

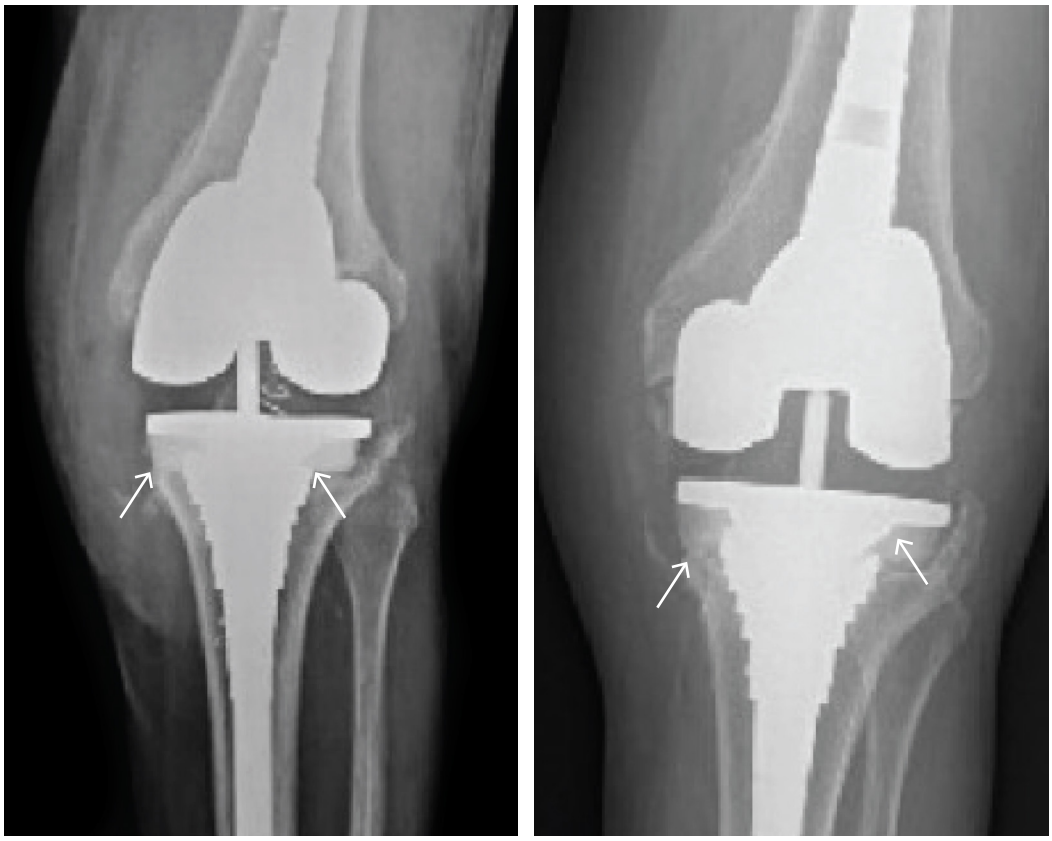


Figure 6. X-ray showing CERAMENT G used to augment a knee implant at the time of implantation.

X-ray images immediately after surgery (left) and 12 months post-operatively (right).

White arrows show where CERAMENT was placed under the tibial component to fill bone voids, and bone remodeling of CERAMENT over time.

Benign Bone Tumors and Tumor-like Lesions

3 KEY STUDIES

1. Horstmann et al. 'Early clinical and radiological experience with a ceramic bone graft substitute in the treatment of benign and borderline bone lesions.' Sci Rep. 2018;8:15384.

Design: Retrospective case series

Indication: Benign or borderline bone lesions

Patient: 34 patients, mean age 32 years [range: 5–69]

Treatment: Curettage and filling with CERAMENT BONE VOID FILLER or CERAMENT G

Center: Musculoskeletal Tumor Section, Department of Orthopedic Surgery, Rigshospitalet, Denmark

Follow-up: 22 months [range: 14–30]

RESULTS

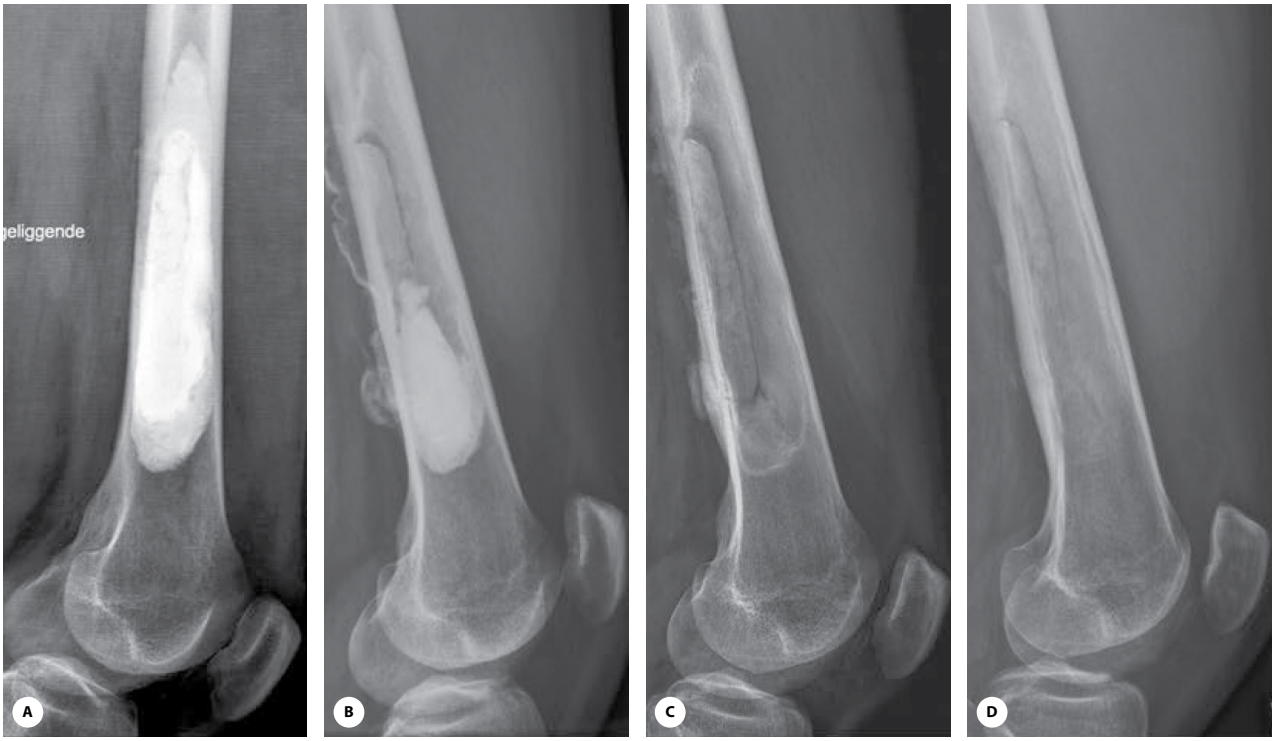
40% (11/28) of patients had **normal radiological appearance of bone cavity**

79% (22/28) **had normal cortical thickness after 1 year**

40% (20/31) of patients were **classed as Neer I or II** (complete or partial healing)

Four patients had recurrence (2 GCT, 2 ABCs)

Figure 7. Example case of a patient with a large femoral enchondroma, treated by curettage and filling of the defect with a combination of CERAMENT G and CERAMENT BONE VOID FILLER through an extended cortical window. Immediately post-operative CERAMENT is clearly visible (A); 6 weeks after surgery bone remodeling has started and in this case there has been some soft-tissue leakage (B), but at the 6 month X-ray this has almost completely resorbed without issue and bone remodeling is continuing (C).12 months after surgery showing the soft-tissue leakage is gone and the edges of the cortical window created during surgery appeared blurred, whilst the posterior and lateral cortex are thicker, indicating remodeling (D).



2. Kotrych et al. 'Preliminary results of highly injectable bi-phasic bone substitute (CERAMENT) in the treatment of benign bone tumors and tumor-like lesions'. Open Med. 2018;13:487-492.

Design: Retrospective case series

Indication: Benign bone tumors and tumor-like lesions

Patient: 33 patients, mean age 47 years [range: 22–74]

Treatment: Curettage and filling with CERAMENT BONE VOID FILLER

Center: Department of Orthopaedics, Traumatology and Orthopaedic Oncology, Pomeranian Medical University, Szczecin, Poland

Follow-up: 13 months [range: 2–13]

RESULTS

All patients showed visible bone remodeling at latest follow-up and no tumor recurrence

VAS decreased from a mean of 5 pre-op to 2 at latest follow-up. MSTS increased from mean 17 preop to mean 31 at latest follow-up

Both **VAS and MSTS improvements were statistically significant** ($p<0.05$)

Benign Bone Tumors and Tumor-like Lesions Cont.

3. Khan et al. 'Efficacy of CERAMENT in large defects created by giant cell tumor'. J Bone Joint Dis. 2018;33(3):10-13.

Design: Prospective case series

Indication: Giant cell tumor

Patient: 14 patients, mean age 25 years [range: 20–30]

Treatment: Curettage and filling with CERAMENT BONE VOID FILLER

Center: Department of Orthopaedics, HIMSR, Jamia Hamdard, New Delhi, India

Follow-up: 6 months

RESULTS

Complete remodeling in all patients in 6 months

No fractures, infection or revision surgery required

White wound drainage was seen in all patients and resolved spontaneously within 2-3 weeks